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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
This Document Relates to: Debra Tinlin, et al. v. C. R. Bard, Inc., et al. CV-16-00263-PHX-DGC	**PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* NO. 2 TO EXCLUDE EVIDENCE OF FDA WARNING LETTER**

Bard's Motion *in Limine* No. 2 seeking to exclude evidence of the FDA's July 13, 2015, warning letter to Bard ("Warning Letter") on the basis of relevance and undue prejudice should be denied.

I. The Warning Letter is Relevant.

Bard's claim that the Warning Letter is irrelevant fails for the following reasons. If the Court denies Plaintiffs' Motion *in Limine* No. 4 (seeking to preclude references to Bard's internal rates of reported complications), Plaintiffs anticipate Bard will attempt to mislead the jury by arguing the FDA's clearance of the Recovery Filter, its decision not to take any enforcement actions against Bard, and/or Bard's own "internal analysis" of its filters' failure rates through December 2016 are proof the Recovery was safe and effective, and Bard acted reasonably in its design, manufacture, warning, etc., of its IVC filters. If this argument is allowed, then Plaintiffs must be allowed to show the FDA issued the Warning Letter relating to Bards' IVC filter line upon discovering reporting and manufacturing issues with same. Although the Warning Letter came after Mrs. Tinlin received her filter, the letter is relevant to show Bard "fail[ed] to establish and maintain procedures for receiving, reviewing, and evaluating complaints . . . adequately." *See* Exhibit A, Hyde Trial Ex. 1680, FDA Warning Letter, July 13, 2015. This evidence, of course, is highly relevant and necessary to rebut Bard's arguments of safety, "99.9 percent" efficacy rates, and false failure rates of only .24%-.84%, which are all based on Bard's inadequate internal review and evaluation of complaints, through December 2016. *See* Plaintiff's MIL No. 4, Dkt. 16579.

The letter is also evidence that Bard failed to properly report to the FDA and failed to submit MDRs that contained complete information, which is relevant to rebutting Bard's frequent claims it provided all necessary information to the FDA. *Id.* For example, sections 7 and 8 of the Warning Letter show Bard failed to properly report adverse incidents involving its filters. This failure is evidence of Bard's pattern of concealment and is relevant and probative to Plaintiffs' failure to warn and punitive damages claims.

In addition to offering evidence of Bard's deficient reporting process and inadequate

disclosures to the FDA, the Warning Letter is an essential piece of evidence to rebut Bard's anticipated suggestion that the FDA took no action and expressed no concerns related to its IVC filters. If Bard is allowed to use the FDA's clearance of its Recovery as a shield, fairness requires that Plaintiffs be allowed to use the Warning Letter to rebut any suggestion that, once the FDA cleared Bard's filters, it had no concerns about them. The FDA's finding that Bard failed in its reporting and handling of cases involving filter failure in patients is of particular relevance given the nature of Plaintiffs' claims concerning failure rates and comparative product performance.[1]

Plaintiffs also anticipate Bard's defense will rely heavily on testimony that it had a detailed complaint handling procedure in place. The Warning Letter is relevant to show, as this Court held in *Jones* and *Hyde*, that the FDA critiqued Bard's complaint handling procedures. *See* Exhibit C, *Hyde v. C.R. Bard et al.* Trial Tr. at 1354:21-1355:6.

Moreover, the Warning Letter is directly on point to several of the issues in this case. Plaintiffs contend Bard failed to properly review, evaluate, track (or trend), perform root cause analysis and report complaints about its IVC filters, leading to the negligent and punitive behavior which caused significant harm to Mrs. Tinlin, as well as unsuspecting patients in the thousands.[2] Section 3 of the Warning Letter admonishes Bard for this very behavior, with section 3a specifically addressing Bard's failure to adequately evaluate for root cause of device failure and implement "appropriate corrective action."

Furthermore, Bard's claim that the Warning Letter "has nothing to do with the Recovery," is disingenuous. The first paragraph of section 3 indicates the violations listed in sections 3a through 3c are merely examples of the failures the FDA uncovered, not the

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[1] This is true regardless of whether Mrs. Tinlin's implanting physician relied upon MAUDE database information in electing to implant the Recovery filter. Mrs. Tinlin's implanting physician clearly testified, 1) he did not know about these serious adverse events Bard was experiencing with its filters or its failure to conduct adequate root cause analysis of same; 2) he expected Bard would disclose such information; 3) he would have wanted to know this information; and 4) such information was necessary for him to conduct a proper risk-benefit analysis before implanting Ms. Tinlin with a Bard Recovery filter. *See* Exhibit B, Joshua Riebe, M.D., Dep. April 4, 2017, at 21:5-22:2, 25:12-16, 26:23-27:18, 28:6-23.

[2] There are over 4,000 cases currently pending in this MDL.

entirety of failures. Section 3a, which identifies Bard's failures to adequately evaluate for root cause and implement appropriate corrective action, is not limited to any one type of filter, but rather Bard's processes concerning its filter lines, including the Recovery. Section 3c identifies violations involving at least 10 patients noted by the FDA wherein the filters are largely unidentified and may very well include Recovery filters.

Finally, this Court previously denied these same claims of irrelevance and prejudice and determined in *Booker*, *Jones* and *Hyde* that the Warning Letter is relevant and admissible, considering the information and claims Bard presents to the jury. *See* Exhibit D, *Booker v. C.R. Bard et al*. Trial Tr. at 1888:2-4, 1888:14-1889:6 (holding Warning Letter relevant concerning evidence of MAUDE database, Bard's internal data, its handling and reporting of adverse events, its reports to the FDA, its root cause analysis, FDA questions or lack thereof, and arguments the FDA never took any action with Bard).

II. The Warning Letter is not unduly prejudicial.

Any prejudice due to evidentiary weight the jury places on a regulatory agency's determinations is invited by Bard, assuming it is allowed to introduce evidence concerning FDA clearance and regulation of its filters or references to its falsely low failure rates. The same goes for Bard's contention that it would be required to spend an inordinate amount of time to place the Warning Letter in context. Any time spent placing the Warning Letter "into proper context" pales in comparison to the amount of time Plaintiffs will spend placing other FDA actions, or lack thereof, "into proper context." Moreover, Bard's acknowledgment that it can put such evidence into context for the jury ameliorates any risk of undue prejudice.

For the foregoing reasons, Plaintiffs respectfully request that Defendants' motion *in limine* to exclude evidence of the FDA's July 13, 2015, warning letter to Bard on the basis of relevance and undue prejudice be DENIED.

RESPECTFULLY SUBMITTED this 12th day of April 2019.

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of April 2019, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine